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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,858	04/14/2000	James McShane	109536.132	9181
7590 09/28/2004 Hollie L. Baker Hale and Dorr LLP 60 State Street Boston, MA 02109			EXAMINER JONES, DWAYNE C	
			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/549,858

Applicant(s)

MCSHANE ET AL.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the remarks of 21JUL2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-23 are pending.
2. Claims 1-23 are rejected.

Response to Arguments

3. Applicant's arguments filed July 21, 2004 have been fully considered but they are not persuasive. Applicant presents the following arguments. First, applicant argues that because Oishi et al. state, "the use of a buffering agent alone or the use of amino acid, amino acid salt or amino acid alkali salt alone provides absolutely no stabilization effect when the substance is blended with benzimidazole compounds", from the translation of Oishi et al. paragraph 16, Oishi et al. teach an amino acid, such as glycine, when used alone does not provide any stabilization effect for a benzimidazole compound. Second, applicant argues that Takechi et al. do not teach of a composition comprised of benzimidazole and the amino acid of glycine. Third, applicant next purports that Takechi et al. discloses sugars are the preferred form of regulators.

4. First, applicant argues that because Oishi et al. state, "the use of a buffering agent alone or the use of amino acid, amino acid salt or amino acid alkali salt alone provides absolutely no stabilization effect when the substance is blended with benzimidazole compounds", from the translation of Oishi et al. paragraph 16, Oishi et al. teach an amino acid, such as glycine, when used alone does not provide any stabilization effect for a benzimidazole compound. The following sentence states,

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"[h]owever, it was discovered that dramatic stabilization of benzimidazole compounds occurs when these two substances are used in conjunction, and that stabilized preparations containing ant ulcer agents are obtained by using these substance in conjunction." Clearly, one having ordinary skill in the art is provided with the motivation to combine the ant ulcer compound of a benzimidazole compound along with glycine and other additional agents. Moreover, the skilled artisan would have been motivated to make these glycine and benzimidazole containing compositions in basic pH ranges in order to maintain the efficacy and stability of the benzimdazole before its use.

Accordingly, the incorporation of a basic material, such as NaOH, is well within the level of the skilled artisan in the pharmaceutical arts. In addition, it is also noted that applicants illustratively define the term tonicity agent with the following list of agents, namely dextrose, sodium chloride, mannitol, glycerin, sucrose (which is also known as the sugar of glucose),, and lactose, (see page 9, lines 3-6). The prior art reference of Oishi et al. specifically recites of compositions that contain omeprazole, with glycine and mannitol, (see paragraphs 9-11 of Oishi et al.). Oishi et al. teach of the same and related ingredients that are instantly claimed, which render the instant invention obvious. Furthermore, applicants recite the word "comprising", which is open-claim language, which embraces the presence of other components. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

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5. Second, applicant argues that Takechi et al. do not teach of a composition comprised of benzimidazole and the amino acid of glycine. Applicant's invention is directed to compositions and methods of stabilizing benzimidazoles with the amino acid of glycine. Similarly, the prior art reference of Takechi et al. also teach of a composition comprised of benzimidazole with the amino acid glycine, as does the instant invention. In addition, Takechi et al. state that glycine is present in basic solutions, which obviously embraces the solutions having a pH of between 10 and 11, (see column 8, lines 6-16). Takechi et al. also teach of the presence of NaOH, (see column 8, lines 6-16). In addition, it is also noted that applicants illustratively define the term tonicity agent with the following list of agents, namely dextrose (which is also known as the sugar of glucose), sodium chloride, mannitol, glycerin, sucrose, and lactose, (see page 9, lines 3-6). Likewise, Takechi et al. teach of including the various agents of mannitol, lactose, sucrose, glucose (also known as dextrose), (see column 8, lines 37-48).

6. Third, applicant next purports that Takechi et al. discloses sugars are the preferred form of regulators. It is first noted that applicants illustratively define the term tonicity agent with the following list of agents, namely dextrose (which is also known as the sugar of glucose), sodium chloride, mannitol, glycerin, sucrose, and lactose, (see page 9, lines 3-6). Likewise, Takechi et al. teach of including the various agents of mannitol, lactose, sucrose, glucose (also known as dextrose), (see column 8, lines 37-48). In addition, the fact remains the instant claims are directed to composition claims with an intended use of the glycine component as well as methods of stabilizing the anti-ulcerative formulation that is comprised of benzimidazole and glycine in a basic

solution. Interestingly, the prior art reference of Takechi et al. also teaches of a composition and methods of stabilizing the benzimidazole compounds with agents that do in fact contain glycine. Moreover, the instant claims are worded with the open-claim language of "comprising", which embraces the presence of other components. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Oishi et al. of H5-194225 is maintained for both the outstanding and above-stated reasons.
9. The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Takechi et al. of U.S. Patent No. 5,536,735 is maintained for both the above-stated and reasons of record.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (703) 872-9306.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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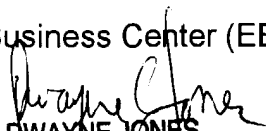
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DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
September 24, 2004